

REMARKS

Claims 1-8 and 10-37 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 7, 8, 10-11, 16-19, 23-26, 28, 29, and 35 have been amended; claim 9 has been cancelled; and claim 36 has been added. Applicants believe that the claim amendments, cancellations, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that they do not limit the range of any permissible equivalents.

Objected Claims

Claims 11, 17, and 23 were objected to because of informalities. Accordingly, Applicants have amended the claims in accordance with the Examiner's suggestions.

In light of the foregoing, Applicants request reconsideration and withdrawal of the claim objections.

§112 Rejection

Claims 19-29 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The rejection states that, with regards to claim 19, it is not certain whether the retainer is part of the invention, since it is said to be "positioned between the tip portion of the end effector and the end portion of the tubular section".

Claim 19 has been amended to address the rejection, changing "positioned" to --positionable--. As claims 20-29 depend from claim 19, Applicants submit that the amendment corrects the stated indefiniteness with regard to these claims, as well.

In light of the foregoing, Applicants request reconsideration and withdrawal of the §112 Rejections.

§102 Rejections

Claims 1-6, 9, 11-12, 15, 17-22, 27, 28, 30, 33 and 35 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,277 to Mollenauer et al. ("Mollenauer"). Applicants submit that the claims are not anticipated by Mollenauer and request that the rejections be withdrawn for the following reasons.

Mollenauer relates to devices for welding suture segments in lieu of tying knots in sutures applied during endoscopic surgery. (Abstract). The welding device is comprised of a long insertion rod 2, with a distal end 3 and a proximal end 4. (Col. 2, lns. 56-58). The distal end carries a pair of grasping jaws 5 and 6 mounted pivotably within the distal end and protruding from the distal end of the insertion rod. (Col. 2, lns. 58-61).). Each jaw 5 and 6 has a grasping face 17 and 18 which opposes the grasping face on the other jaw, and the jaws may be closed to bring the grasping faces into contact or close proximity. (Col. 3, lns. 21-24). The grasping face of each jaw includes resistive heating elements 19 and 20 which are connected to an appropriate power supply through electrical wires that run through the jaws and the insertion rod to electrical connector 21 in the handle. (Col. 3, lns. 24-28).

A snare 8 including a snaring portion 9 mounted on the distal end of a snare rod 10 is slidably and rotatably disposed within the lumen 11 in the d insertion rod 2. (Col. 2, lns. 61-64). The snare portion 9 is comprised of two arcuate branches of resilient metal or plastic, with each branch extending distally from the snare rod to curve first outwardly from the long axis of the snare rod and then inwardly toward the long axis of the snare rod to join together at their distal tips. (Col. 3, lns. 12-16).

The snare provides a means for initially grasping loose suture ends and drawing the suture ends into close proximity to the jaws. (Col. 2. ln. 1 -- col. 3, lns. 3). The jaws provide a second means for grasping the suture ends after they have been picked up by the snare. (Col. 3. lns. 3-4). In FIG. 3 of Mollenauer the distal end of the insertion rod is illustrated in proximity to a surgical incision 40 which has been stitched with suture 41. (Col. 4. lns. 10-12). The snare loop 9 has been

has been extended distally from the lumen 11 in the insertion rod 2, and has been manipulated by the surgeon to snare the ends 47 and 48. (Col. 4. Ins. 18-21).

FIG. 4 of Mollenauer illustrates that the snare and snare rod have been pulled proximally to draw the suture ends into the lumen 11, drawing the welding portions 45 and 46 into the space between the jaws. (Col. 4. Ins. 21-24). The snare rod has been rotated within the lumen to coil the fusing portions of the suture ends into a length of intertwined suture segments, referred to as the twist 49. (Col. 4. Ins. 24-27).

In FIG. 5 of Mollenauer, the surgeon has closed the jaws upon the twist 49. (Col. 4. Ins. 27-28). The suture may be tensioned as desired by the surgeon prior to melting by closing the jaws firmly on the suture while drawing the snare proximally, then closely the jaws tightly so that the suture is held in properly tensioned position while the weld is accomplished. (Col. 4. Ins. 32-36). The surgeon then applies heating power to the heating elements in the jaws by operating the switch 25 in the handle. (Col. 4. Ins. 36-38). The heat fuses the weld portions of each suture into mass that firmly holds the standing parts together, just as would a well tied knot. (Col. 4. Ins. 38-40). When the jaws are opened, the melted twist is released from the jaws and remains in place within the body, just as would the knot. (Col. 4. Ins. 47-49).

In FIG. 6 of Mollenauer, the snare is comprised of two diverging arms 50 extending from the snare rod and forming a Y together with the snare rod. (Col. 4. Ins. 60-62). The arms of the grasper may be closed upon withdrawal into the lumen of the insertion rod. (Col. 4. Ins. 62-62-64).

FIG. 8 of Mollenauer illustrates a rotary embodiment of the suture welding device. (Col. 5. Ins. 5-6). The outer tube 54 of the insertion rod houses an inner tube 55 which is rotatable within the outer tube. (Col. 5. Ins. 7-9). On the distal end of the inner tubes, heating anvil 56 and grasping surface 57 are formed from a radially extending boss. (Col. 5. Ins. 9-11). The inner and outer tubes have a small slot 58 which opens on the distal extremity of each tube. (Col. 5. Ins. 11-13). The heating anvil is mounting on one edge of the slot of the inner tube, and extends radially outwardly from the center axis of the tube and into the slot of the outer tube. (Col. 5. Ins. 17-20).

The grasping surface of the outer tube is disposed on the slot wall of the outer tube slot which opposes the anvil, so that rotation of the inner tube rotates the anvil into mating relationship with the grasping surface of the outer tube. (Col. 5, lns. 20-24). A snare 10 is slidably and rotatably disposed within the insertion rod 2, within a lumen 63 in the inner tube 55. (Col. 5, lns. 28-30

With reference to Fig. 9 of Mollenauer, the surgeon has tensioned the sutures as desired by pulling the appropriate amount of suture into the insertion rod and/or twisting the suture weld portions together. (Col. 5, lns. 51-54). Tensioning can be accomplished by twisting the standing parts of the suture and/or drawing the suture proximally in to the rod until the desired degree of tension is obtained. (Id).

As such, Mollenauer discloses a device for welding suture segments together. The device includes a snare for capturing the suture segments and drawing the suture segments into the device, such that the suture segments are positioned between two jaws. The jaws include heating elements which apply heat to the suture segments, melting the segments together. The snare is attached to a handle which the surgeon pulls to draw the suture segments between the two jaws. The handle can be rotated such that the suture segments can be twisted together.

Therefore, Mollenauer fails to disclose that the snare includes a bias member that tensions the suture. The snare is manually pulled by the surgeon to draw the suture segments between the jaws. Furthermore, Mollenauer fails to disclose that the jaws are configured to receive a retainer there between and an energy source operably connected to the jaws for transmitting an energy to the retainer for attachment to the suture.

Mollenauer only discloses that the snare (8) pulls the suture segment through the jaws. The snare itself is not positioned between the jaws, nor do the jaws apply an energy to the snare to bond the snare to the suture segments. Mollenauer only discloses that the jaws bond the suture segments together.

Additionally, the suture of Mollenauer includes a meltable core 75 covered by a melt resistant porous sheath 76. (See Fig. 10 and Col. 6, lns. 5-7). Upon application of heat sufficient to

to melt the cores, the core material flows through the porous sheath and flows into the core material flowing from the adjoining suture segments. (Col. 6, Ins. 7-10).

As such, the suture segments are only bonded to each other, where the suture consists of the meltable core and the melt resistant sheath, and the jaws apply a heat to only melt the meltable core to bond the suture segments together. Mollenauer fails to disclose that the jaws apply heat for the attachment of a retainer to the suture.

Finally, as the suture consists of the meltable core and the melt resistant sheath and the snare is used to pull the suture segments through the jaws, Mollenauer fails to disclose a suture tensioner which maintains a substantially constant tension on the suture through a retainer during the attachment of the retainer to the suture. Specifically, as the snare is used to pull the suture segments through the jaws and is not itself positioned between the jaws for attachment to the suture, the snare cannot maintain a substantially constant tension on the suture segments through itself for attachment of itself to the suture segments. Additionally, as the meltable core and meltable sheath are the components of the suture, the snare simultaneously pulls the meltable core and meltable sheath through the jaws, and cannot maintain a substantially constant tension on the meltable cores with respect to the non-meltable sheath.

In contrast, in the present invention, a suture and a suture retainer are positioned relative to body tissue. Ultrasonic vibratory energy is utilized to heat the suture retainer and effect a bonding of portions of the suture retainer to each other and/or to the suture. (Abstract).

Although the suture retainer 34 could have many different constructions and configurations, in the illustrated embodiment of the invention, the suture retainer 34 is integrally formed as one piece and has a spherical configuration. ([0090]). A cylindrical central passage 76 extends axially through the suture retainer 34 between upper and lower (as viewed in FIG. 2) polar regions of the spherical suture retainer. (Id). The two sections 38 and 40 of the suture 32 extend through the passage 76. (Id). The suture retainer 34 is formed separately from the suture 32 and is initially disconnected from the suture. (Id).

The suture retainer 34 is pressed downward against the body tissue 46 with a predetermined

predetermined force, indicated schematically by an arrow 106 in FIG. 3, while a predetermined tension, indicated schematically by the arrows 102 and 104, is maintained in the suture 32. ([0123]). The force transmitted from the suture 32 and suture retainer 34 to the layers 46 and 48 of body tissue presses them together and, to some extent, compresses the layers of body tissue. (Id). This results in the layers of body tissue being held in linear apposition and being compressed to promote healing of the layers 46 and 48 of body tissue. (Id).

The suture retainer 124 slides downward (as viewed in FIG. 4) along the suture 112 under the influence of the force application member 140. ([0148]). At this time, the suture 112 is tensioned by the force application assembly 130 so that the portion of the suture extending between the suture anchor 120 and the force application assembly 130 is straight, as illustrated in FIG. 4. (Id).

Referring to FIGS. 63 and 64, a suture tensioner 1350 is provided on the tubular section 1322. ([0540]). The suture tensioner 1350 places a substantially constant tension on a suture lead. (Id). The suture tensioner 1350 includes a projection 1352 having a pulley portion 1354 and a cleat portion 1356. (Id). The suture is threaded about the pulley portion 1354 and pulled downward, being cinched in the cleat portion 1356. (Id). The suture tensioner 1350 includes a bias member 1358 allowing the suture tensioner 1350 to be displaced about 0.5 inches on the tubular section 1322 and providing a 2-10 lb. tension to the suture. (Id). The bias member 1358 can be a spring 1360 within the suture tensioner 1350, interposed between the suture tensioner 1350 and a ring key 1362. (Id). It is envisioned that one or more suture tensioners 1350 can be provided on the tubular section 1322. (Id). The use of the suture tensioner 1350 to hold the suture, *freed up the surgeon from holding the suture* [emphasis added], maintaining the predetermined force on the suture during the connection of the suture retainer to the suture. (Id).

As such the present invention is directed to a surgical device for attaching a retainer to a suture. The surgical device can press the retainer against the body tissue and tension the sutures through the retainer with different forces. The surgical device includes a suture tensioner having a suture bias member operative to maintain a substantially constant tension on the suture through the

the retainer, during attachment of the suture to the retainer. Mollenauer fails, at least, to show these claimed elements.

Claim 1 recites, *inter alia*, a surgical device for attaching a retainer to a suture for securing tissue in a patient's body, comprising: a first member including a first compression element; a second member including a second compression element, the second member being in movable relation with the first member from a first position to a second position, wherein the first compression element and the second compression element are configured to receive the retainer there between; a suture tensioner including a suture bias member positioned on the second member and configured to receive the suture, maintaining a substantially constant tension on the suture through the retainer during attachment of the retainer thereto; and an energy source operably connected to the first compression element for transmitting an energy to the retainer for attachment to the suture. Independent claims 17 and 35 include substantially similar limitations.

Accordingly, Applicants respectfully submit that claims 1, 17, and 35 are patentable over Mollenauer. As claims 2-6, 11, 12, and 15 depend from claim 1, and claims 18-22, 27, 28, 30 and 33 depend from claim 17, these dependent claims necessarily include all the elements of their base claims. Accordingly, Applicants respectfully submit that the dependent claims are allowable over Mollenauer for the same reasons.

In light of the foregoing, Applicants request reconsideration and withdrawal of the section 102 rejection.

§103-Rejections

Claims 10 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mollenauer. Claims 13, 14, 31, and 32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mollenauer in view of U.S. Patent no. 5,306,280 to Bregen et al. ("Bregen").

As previously discussed, claims 1 and 17 are submitted to be patentable over Mollenauer. As Bregen does not remedy the deficiencies of Mollenauer with respect to the invention as set forth in

forth in claims 1 and 17, claims 1 and 17 are submitted to be patentable over the cited prior art, either alone or in combination. As claims 10, 13 and 14 depend upon claim 1, and claims 29, 31 and 32 depend upon claim 17, and include all of the elements therein, Applicants submit that these dependent claims are allowable at least for the same reasons.

In light of the foregoing, Applicants request reconsideration and withdrawal of the section 103 rejections.

Allowable Subject Matter

Claims 7, 8, 16, and 34 were objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Furthermore, claims 23-26 were indicated as being allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in the Office Action and to include all of the limitations of the base claim and any intervening claims.

Applicants have added new claim 36 which incorporates the subject matter of claim 7, including all of the elements of the base claim and any intervening claims. Applicants have rewritten claim 16 as required by the Examiner. Accordingly, Applicants submit that claims 16 and 36 are in condition for allowance.

Furthermore, as claims 7, 8, 23-26, and 34 depend from claims 1 and 17, these claims are submitted to be allowable at least for the same reasons.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Applicant: Bonutti et al.
Application No.: 10/797,685
Examiner: J. Woo

A fee of \$200.00 under 37 C.F.R 1.16(h) for two additional independent claims is believed due and is being paid via Credit Card Payment. However, please charge any additional fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A04-026).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul D. Bianco". The signature is fluid and cursive, with a large initial "P" and a stylized "B".

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